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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,043	07/18/2003	Mark C. Estes	91-01 C7	6442

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,043	ESTES ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/18/2004 (AMENDMENT)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 19,21,24,25 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Sanders et al. ('802).

As to claim 19, Sanders et al. disclose a system for delivering pressurized gas to an airway of a patient comprising: a pressure generating system (fig.1); a conduit (20) having a first end operatively coupled to the pressure generating and a second end; a patient interface (22) operatively coupled to the second end of the conduit, and a sensor (28) operatively coupled to the pressure generating system, the conduit, or the patient interface, wherein the sensor is adapted to detect a parameter (i.e. inhalation and

exhalation) indicative of a patient breathing into the patient interface, a processor (34) operatively coupled to the sensor and the pressure generating system, wherein the processor is programmed to determine whether a patient is breathing into the patient interface based on the output of the sensor (col.7, lines 8-26), wherein the processor is programmed to activate the pressure generating system responsive a determination that such a patient is breathing into the patient interface so that pressurized gas is generated by the pressure generating system (col.6, lines 35-48).

As to claim 21, Sanders et al. disclose the pressure generating system to comprise a pressure generator (16) adapted to generate a flow of gas; and a pressure controller (20) cooperable with the pressure generator to control the flow of gas within the conduit at variable pressures.

As to claim 24, Sanders et al. disclose the processor (34) being programmed to cause the pressure generating system to adjust the pressure of the pressurized gas generating by the pressure generating in to synchronize the generation of the pressurized gas with an occurrence of alternating inspiratory and expiratory phases of such a patient's respiration in a manner to maintain the positive pressure in the patient's airway during a sequence of the inspiratory and expiratory phases, with the magnitude of pressure during at least a portion each expiratory phase being less than the magnitude of pressure during at least a portion the immediately preceding inspiratory phase (col.3, lines 24-36, lines 48-54, and lines 56-65).

As to claim 25, Sanders et al. disclose an exhaust port (24) defined in at least one of the conduit and the patient interface (22).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders ('802) in view of Giorgini et al. ('592).

The difference between Sanders et al. and claim 20 is the processor being programmed to deactivate the pressure generating system responsive to a determination that the patient is not breathing into the patient interface and to cease generation of the pressurized gas by the pressure generating system.

Giorgini et al. teach deactivation (6) the pressure generating system responsive a determination that such a patient is not breathing into the patient interface to cease generation of the pressurized gas by the pressure generating system (col.2, line 65-col.3, line 3; col.6, lines 26-33 and Abstract lines 4-5) for the purpose of preventing wasting of breathable gas and to prevent a patient from being subjected to dangerously high gas pressures.

It would have been obvious to modify the processor to deactivate the pressure generating system responsive to a determination that the patient is not breathing into the interface because it would have provided a means for preventing wasting of breathable gas and to prevent a patient from being subjected to dangerously high gas pressures as taught by Giorgini et al..

5. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. ('802) in view of Servidio et al. ('819).

The difference between Sanders et al. and claim 22 is pressure ramping means for executing a ramp cycle in which the pressure of the pressurized gas increases over time.

Servidio et al., in a system for delivering pressurized gas to an airway of a patient, teach a pressure ramping means (21,22) for executing a ramp cycle in which the a pressure of the pressurized gas increases over time (fig.5) for the purpose of gradually increasing the breathable gas pressure to allow a patient to acclimate comfortably to the increased pressure (col.4, lines 26-29; col.3, lines 34-40).

It would have been obvious to modify Sanders to include a pressure ramping means for executing a ramp cycle in which the pressure of the pressurized gas increases over time because it would have provided a means for gradually increasing the breathable gas pressure thereby allowing a patient to acclimate comfortably to the increased pressure as taught by Servidio et al..

As to claim 23, Servidio et al. teach the ramping means includes a manually actuatable mechanism (21,22) that, when actuated, causes the ramping means to execute the ramp cycle.

Response to Arguments

Applicant's arguments filed 06/18/2004 have been fully considered but they are not persuasive. The language of claims 19-25 is not commensurate with applicant's arguments that the instant application is directed to an automatic ON/OFF capability

because the specific language "...substantially inactive..." is not limited to an OFF state; rather, it includes a state having some activity that is consistent with the base flow only state of Sanders et al.. Further, the processor of Sanders et al. controls the movement of the system from the substantially inactive state to the active state.

Applicant's arguments regarding the propriety of the combination of Sanders et al. and Giorgini et al. are disagreed with because one of ordinary skill would be concerned with a patient receiving dangerously high pressures if that patient were not breathing or not breathing properly in Sanders et al. and one of ordinary skill would be concerned with wasting of oxygen if a patient became disconnected from the mask of Sanders et al.; consequently, one of ordinary skill would be motivated to combine the safety features and oxygen conserving features of Giorgini et al. with Sanders et al..

Applicant's arguments regarding the combination of Sanders et al. with Servidio et al. are disagreed with because the claim language "...substantially inactive..." is not limited to an OFF state; rather, it includes a state having some activity that is consistent with the base flow only state of Sanders et al..

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

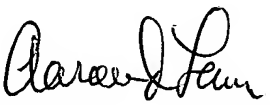
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 20, 2004